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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/642,587 | 08/19/2003 | Samuel Bogoch | 9425/468031 | 2933 |

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| EXAMINER | |
|---|---|
| EMCH, GREGORY S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/642,587 | BOGOCH ET AL. | |
| | Examiner | Art Unit | |
| | Gregory S. Emch | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *6-11,13-19,21,22 and 24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-11,13-19,21,22,and 24-31* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Formal Matters*

Claims 1-5, 12, 20 and 23 were canceled and new claims 18-33 were added in the preliminary amendment dated 19 August 2003. Claims 6-11, 13-19, 21, 22 and 24-31 are pending.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6-8 are drawn to a method of inhibiting or preventing the attachment of influenza virus particles to the cells of a human patient comprising administering to the patient a therapeutically effective amount of a glycoconjugate, classified in class 514, subclass 8, for example.

II. Claims 9-11 are drawn to a method of treating schizophrenia comprising administering to a patient in need thereof a therapeutically effective amount of a D-glucosamine-HCl to thereby increase the concentration of brain glycoconjugates in said patient, classified in class 514, subclass 62, for example.

III. Claims 13-15 and 24-27 are drawn to a purified monoclonal antibody which specifically recognizes a peptide having the amino acid sequence of SEQ ID NO: 2, a therapeutic composition for increasing anti-malignin antibody concentration in a patient in need thereof comprising a peptide

selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof, associated kits, and an isolated nucleic acid encoding a peptide comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, classified in class 530, subclass 388.1, for example.

IV. Claims 16-17 are drawn to a method of treating chronic viral infection comprising administering to a patient in need thereof a therapeutically effective amount of a peptide selected from the group consisting of a peptide of SEQ ID NO: 1, a peptide of SEQ ID NO: 2, aglycoprotein 10B, and combinations thereof, classified in class 514, subclass 13, for example.

V. Claims 18-19, 22 and 28-30 are drawn to a method of diagnosing cancer associated with chronic viral disease in a patient comprising detecting transformation to malignant cells in said patient, said transformation being detected by a determination of an elevated level of aglycoprotein 10B antibody in blood or aglycoprotein antigenic peptides in blood or tissue of said patient, classified in class 435, subclass 7.1, for example.

VI. Claim 21 is drawn to a method of treating brain tumors comprising administering to a patient in need thereof a therapeutically effective amount of diphenylhydantoin to thereby increase the level of brain glyoconjugates in said patient, classified in class 514, subclass 23, for example.

VII. Claim 31 is drawn to a method diagnosing schizophrenia in a patient which comprises measuring the amount of neuraminic acid and hexosamine in glycoproteins isolated from the cerebral spinal fluid of said patient, classified in class 436, subclass 161, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I and each of II, IV, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires preventing the attachment of influenza particles to the cells of a human a patient, which is not required by any one of Inventions II, IV, V, VI and VII. Invention II requires treating schizophrenia, which is not required by any one of Inventions I, IV, V, VI and VII. Invention IV requires treating viral infection with peptides of SEQ ID NOs: 1 or 2, which is not required by any one of Inventions I, II, V, VI and VII. Invention V requires diagnosing cancer, which is not required by any one of Inventions I, II, IV, VI and VII. Invention VI requires treating brain tumors with diphenylhydantoin, which is not required by any one of Inventions I, II, IV, V and VII. Invention VII requires diagnosing schizophrenia by measuring neuraminic acid and hexosamine in glycoproteins, which is not required by any one of Inventions I, II, IV, V and VI. Therefore, a search and examination of all of these methods in one patent application

would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Invention III and each of I, II, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Invention III and each of I, II, VI and VII are unrelated product and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, VI and VII do not recite the use or production of the peptides and nucleic acids of Invention III.

Inventions III and each of IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Invention III can be used in *in vivo* imaging techniques.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of

35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph. D.
Patent Examiner
Art Unit 1649
March 19, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER